

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 21-1015-JLH
)	
SAREPTA THERAPEUTICS, INC.)	DEMAND FOR JURY TRIAL
)	
Defendant.)	
)	
<hr/>		
SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD.)	
and NS PHARMA, INC.,)	
)	
Plaintiff/Counter-Defendants.)	

[PROPOSED] JOINT PRETRIAL ORDER

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Dated: April 29, 2024

**LIST OF EXHIBITS IN
JOINT PRETRIAL ORDER**

ABBREVIATIONS AND DEFINITIONS -- Exhibit A

Joint

ASSERTED CLAIMS

Joint -- Exhibit 1

STATEMENT OF FACTS WHICH ARE ADMITTED AND REQUIRE NO PROOF

Joint -- Exhibit 2

ISSUES OF FACT THAT REMAIN TO BE LITIGATED AND EXPECTED PROOFS

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Sarepta/UWA -- Exhibit 4

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This matter comes before the Court at a final pretrial conference held pursuant to Rule 16 of the Federal Rules of Civil Procedure. The Pretrial Conference is scheduled for May 6, 2024. D.I. 143 ¶ 19. A five-day jury trial is scheduled to begin on May 13, 2024.

I. NATURE OF THE CASE

This is an action involving patent infringement, patent invalidity, inequitable conduct, and breach of contract, and *Walker Process* fraud. Plaintiff Nippon Shinyaku and Counter-Plaintiffs Sarepta and UWA initially asserted claims for patent infringement of the NS Patents and the Wilton Patents, respectively.

Nippon Shinyaku asserted claims for patent infringement of the NS Patents against Sarepta arising out of Sarepta's manufacture, use, sale, offers to sell within the United States, and/or importation into the United States of VYONDYS 53®, also known as golodirsen, and Sarepta's intentional encouragement of physicians to administer VYONDYS 53®. Nippon Shinyaku alleged that Sarepta's infringement is willful. Nippon Shinyaku seeks a reasonable royalty for Sarepta's alleged past and future infringement under 35 U.S.C. § 284 as well as lost profits. Nippon Shinyaku also seeks pre-judgment and post-judgment interest, an award of enhanced damages for alleged willful infringement, and an award of attorneys' fees and costs.

Sarepta and UWA asserted counterclaims for infringement of the Wilton Patents against Nippon Shinyaku and Counter-Defendant NS Pharma arising out of their manufacture, use, sale, offers to sell within the United States, and/or importation into the United States of VILTEPSO®, also known as viltolarsen, and their intentional encouragement of physicians and patients to administer VILTEPSO®. Sarepta and UWA alleged that Nippon Shinyaku's and NS Pharma's infringement is willful. Sarepta and UWA seek a reasonable royalty for Nippon Shinyaku's and NS Pharma's alleged past and future infringement under 35 U.S.C. § 284 as well as lost profits.

Sarepta and UWA also seek pre-judgment and post-judgment interest, an award of enhanced damages for alleged willful infringement, and an award of attorneys' fees and costs.

In Nippon Shinyaku's operative complaint (D.I. 86), Nippon Shinyaku further alleges—and the Federal Circuit has held—that Sarepta breached a Mutual Confidentiality Agreement ("MCA", D.I. 1-2) by filing certain petitions for *inter partes* review. Nippon Shinyaku has obtained preliminary injunctive relief relating to its breach of contract claim, but further seeks permanent relief and money damages. Nippon Shinyaku also asserts claims for declaratory judgment of invalidity of the Wilton Patents.

In its Answer (D.I. 328), Sarepta denied that it is liable for the asserted causes of action and asserted a counterclaim for declaratory judgment of invalidity of the NS Patents, as well as counterclaims for breach of contract and unenforceability of the NS Patents due to inequitable conduct.

Nippon Shinyaku and NS Pharma answered Sarepta's and UWA's respective counterclaims, denying they are liable for the asserted causes of action. D.I. 344. Additionally, Nippon Shinyaku and NS Pharma asserted counterclaims against Sarepta for unenforceability of the Wilton Patents due to inequitable conduct and for *Walker Process* fraud based on Sarepta's alleged violations of the Sherman Act, 15 U.S.C. §§ 1 *et seq.* by asserting patents that were allegedly obtained by fraud on the USPTO against Nippon Shinyaku and NS Pharma in an attempted effort to unlawfully acquire or maintain monopoly power through improper means. Sarepta answered Nippon Shinyaku's and NS Pharma's counterclaims, denying it is liable for the asserted causes of action. D.I. 347. Sarepta further moved to bifurcate and stay Nippon Shinyaku's and NS Pharma's *Walker Process* fraud claim, (D.I. 345), and Nippon Shinyaku and NS Pharma opposed this motion (D.I. 356).

Sarepta later voluntarily dismissed in part its defenses of no direct infringement, induced infringement, and contributory infringement of claims 1-3 of U.S. Patent No. 10,385,092, claims 1-2 of U.S. Patent No. 10,407,461, and claims 1-2 of U.S. Patent No. 10,487,106 (D.I. 328 at 26, Third Defense) with prejudice, as well as voluntarily dismissing in part its defenses of induced and contributory infringement of claims 1-12 of U.S. Patent No. 10,647,741 and claims 1-4 of U.S. Patent No. 10,662,217 (D.I. 328 at 26, Third Defense) with prejudice. D.I. 475, ¶¶ 1-2.

Nippon Shinyaku and NS Pharma later voluntarily dismissed in part their counterclaim of *Walker Process* fraud under Section 2 of the Sherman Act (D.I. 344, Counterclaim Claim XI) to the extent it relates to actual monopolization with prejudice. Nippon Shinyaku and NS Pharma are proceeding with their *Walker Process* fraud Counterclaim Claim XI to the extent it relates to attempted monopolization. D.I. 475, ¶ 3.

On April 18, 2024, the Court granted-in-part Sarepta’s motion to bifurcate and stay Nippon Shinyaku’s and NS Pharma’s *Walker Process* fraud claim. D.I. 529. The Court bifurcated “NS’s antitrust claim from the substantive patent issues for trial.” *Id.* The Court further ordered, based on the parties agreement “that both sides’ inequitable conduct claims may properly be tried to the bench” and “that the Court’s findings and conclusions regarding NS’s inequitable conduct claim will be binding on the parties with respect to the inequitable conduct elements of NS’s Walker Process antitrust claim.” *Id.*; *see also* Apr. 18, 2024 Status Conference Tr. at 8:11-9:6. The Court ordered that there will be a “bench trial on inequitable conduct . . . with evidence pertaining solely to inequitable conduct being presented to the Court after the jury is released [each day] and/or while the jury is deliberating.” *Id.*

In this pleading, Nippon Shinyaku and Sarepta and UWA withdraw their claims of infringement of specified patent claims (*see infra* § XV). As a result, Nippon Shinyaku now asserts

no more than five claims from the NS Patents and Sarepta now asserts no more than two claims from the Wilton Patents. Sarepta also withdraws its breach of contract claim (*see infra* § XV).

II. JURISDICTION

The Court's subject matter jurisdiction is not disputed and is based on 28 U.S.C. §§ 1331, 1332(a), 1367(a), 1338(a), 2201, and 2202. No party disputes personal jurisdiction for purposes of this action.

III. FACTS

A. Uncontested Facts

1. A joint statement of uncontested facts is set forth in **Exhibit 2**. These proposed uncontested facts require no proof at trial and will become part of the evidentiary record in this case. Subject to the Court's approval, any party, with prior notice to the other party, may read any or all of the uncontested facts to the jury or Court, as long as entire facts are read (i.e., the entire numbered paragraph) and will be charged for the time used to do so. The parties reserve the right to modify or supplement the joint statement of uncontested facts to the extent necessary before they are entered into the evidentiary record to reflect fairly the Court's rulings on any motions or subsequent orders of the Court, or by agreement of the parties.

2. The parties agree that any use of "NS" at trial to refer collectively to Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. is not a waiver or admission of any kind, including an admission that Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. are not separate entities. It remains Nippon Shinyaku's burden to establish that it, the actual plaintiff asserting the NS Patents, rather than NS collectively, is entitled to collect lost profits.

B. Statement of Contested Facts to be Litigated at Trial

3. Nippon Shinyaku's and NS Pharma's statement of issues of fact that remain to be litigated and expected proof is attached as **Exhibit 3**.

4. Sarepta's and UWA's statement of issues of fact that remain to be litigated and expected proof is attached as **Exhibit 4**.

5. The parties reserve the right to modify or supplement their statements of fact that remain to be litigated to the extent necessary to reflect fairly the Court's rulings on any motions or subsequent orders of the Court or by agreement of the parties.

IV. ISSUES OF LAW

6. Nippon Shinyaku's and NS Pharma's statement of issues of law that remain to be litigated is attached as **Exhibit 5**.

7. Sarepta's and UWA's statement of issues of law that remain to be litigated is attached as **Exhibit 6**.

8. The Court's anticipated rulings on the pending summary judgment and *Daubert* motions and anticipated motions *in limine* will likely impact the issues of law to be litigated.

V. EXHIBITS

A. Exhibits

9. Nippon Shinyaku's and NS Pharma's trial exhibit list is attached as **Exhibit 7**. Nippon Shinyaku and NS Pharma identified their exhibits starting with PTX1. Nippon Shinyaku and NS Pharma reserve the right to rely on additional exhibits for the purposes of impeachment. Exhibits relied upon solely for purposes of impeachment shall not be admitted into evidence unless identified on a trial exhibit list.

10. Sarepta's and UWA's trial exhibit list is attached as **Exhibit 8**. Sarepta and UWA identified their exhibits starting with DTX1. Sarepta and UWA reserve the right to rely on

additional exhibits for purposes of impeachment. Exhibits relied upon solely for purposes of impeachment shall not be admitted into evidence unless identified on a trial exhibit list.

11. A list of the joint trial exhibits is attached as **Exhibit 9**. Joint trial exhibits will be identified with JTX numbers starting with JTX1.

12. To the extent that there are identical exhibits identified by distinct numbers on the parties' exhibit lists that are offered and accepted into evidence at trial, the parties shall meet and confer to ensure that such exhibits are subsequently referred to by a single exhibit number. The parties reserve the right to admit PTX and DTX versions of the same document.

13. The descriptions of the documents in Exhibits 7, 8, and 9 are for the convenience of the parties and the Court only and do not constitute admissions about the content or admissibility of the documents described, or other aspects of the documents.

14. A side's failure to introduce any exhibit appearing on its list shall not be commented on during trial.

15. The parties have entered into a stipulation regarding document authenticity, which they incorporate fully herein by reference. *See* D.I. 510.

16. Each party may use an exhibit that is listed on the other side's exhibit list, to the same effect as though it were listed on its own side's exhibit list, subject to any evidentiary objections. Any exhibit, once admitted, may be used equally by any party subject to any limitations as to its admission into evidence. The listing of a document on a side's exhibit list is not an admission that such document is relevant or admissible when offered by the opposing side for the purpose that the opposing side wishes to enter the document into evidence. The fact that an exhibit is listed on a side's exhibit list does not mean that side believes the exhibit would be admissible if offered by the other side. If a party attempts to introduce an exhibit listed only on the other side's

exhibit list, the listing side reserves the right to object to such introduction, and they need not list objections to their own exhibits as part of the Pretrial Order. In addition, each party reserves the right to make objections under Federal Rules of Evidence 104, 105, 602, and 802 to any evidence offered by the other side, at the time such evidence is offered, in view of the specific context in which such evidence is offered.

17. Any date listed on an exhibit list is provided for convenience only and is neither evidence nor an admission of the date of the document, and failing to list a date on an exhibit list is neither evidence nor an admission of whether the document is dated.

18. Legible photocopies of United States patents and their corresponding applications may be offered and received into evidence in lieu of certified copies thereof, subject to all other objections which may be made to the admissibility of certified copies.

19. Unless a genuine question is raised as to the authenticity of the original, or in circumstances it would be unfair to admit the copy in lieu of the original, a duplicate of any document or photograph may be marked for identification, and, if otherwise admissible, offered and received into evidence with the same force and effect as the original, subject to any and all objections as could be made to the original, and on condition that the original of any such duplicate, if within custody or control of the offering party, be available for inspection at the trial by 7:00 pm two days before such duplicate is first used.

20. The parties agree that documents produced during the discovery phase by the parties or from third parties under subpoena during the discovery phase of this litigation and identified in **Exhibits 7, 8, or 9** to this Order are presumed *prima facie* genuine and authentic as set forth in the parties' stipulation (D.I. 510). Nothing, however, shall prohibit a party from offering evidence to rebut the presumption.

21. Documents with writing in a language other than English must include a translation, which translation must be provided as part of the pretrial exchanges to the extent possible, but no later than **2:00 p.m.**¹ on the Wednesday before the first day of trial (i.e. May 8, 2024), and all supplemental translations must be received by that time. The Exhibit list shall include a column indicating which documents are foreign language and include translations. Objections to the form or substance of translations must be made one week before trial begins for all translations exchanged as part of the parties' pretrial exhibit exchange prior to the week before trial. Insofar as any supplemental translation exhibits are added, objections to the form or substance of translations must be made within two (2) days of the date the translation is provided and added to the exhibit list.

22. This Order contains the parties' good faith efforts to identify the universe of exhibits to be used in any party's case. The parties agree to forego exhibit objections prior to the submission of the Pretrial Order while reserving the right to make objections to any exhibits in accordance with the provisions specified herein including objection to exhibits listed on the parties Joint Exhibit List (**Exhibit 9**). To the extent supplemental exhibits are identified, the parties agree to disclose any supplemental exhibits promptly after identification. Reasonable supplementation of exhibit lists will be permitted until **2:00 p.m.** on the Wednesday before the first day of trial (i.e. May 8, 2024), and all supplemental exhibits must be received by that time. After that time, further supplementation shall only be permitted by agreement of the parties, with good cause shown, or with leave of the Court. Objections to the supplemental exhibits shall be due no later than 7:00 p.m. the night before the first day of trial. The parties reserve the right to offer additional exhibits for impeachment. Subject to other provisions of this Order, no party shall be permitted to offer as

¹ All times are listed in Eastern Daylight Time.

evidence any exhibit not present on an exhibit list absent good cause shown or by agreement of the parties, except that documents, deposition transcripts, or portions thereof, or other items, not specifically identified herein or offered into evidence, may be used at trial for purposes of impeachment or rehabilitation, if otherwise competent for such purposes. Exhibits not specifically included in Exhibits 7, 8, or 9 may not be used for rebuttal or reply purposes.

23. Unless otherwise stipulated among the parties, no exhibit will be admitted unless offered into evidence through a witness, who must at least be shown the exhibit. Exhibits may not be published, displayed, or otherwise shown to the jury until after evidentiary objections to an exhibit have been resolved by the Court. Once objections are resolved, counsel may publish exhibits to the jury without requesting to do so. By **7:30 p.m.** on a trial day, the parties will exchange lists of exhibits that were used that day. Disputes on the list (which will not include evidentiary objections, those having been resolved before the exhibit was published to the jury) will be provided no later than **9:00 p.m.** that day. The parties will meet and confer on the disputes by **10:00 p.m.** The following morning no later than **8:30 a.m.**, the parties will provide a list to the Court of the agreed-upon exhibits to be formally entered into evidence. Once admitted, counsel may publish exhibits to the jury without requesting to do so.

24. Provided they are not otherwise objected to, exhibits may be entered through expert witnesses.

25. Exhibits not objected to will be received into evidence without the need for additional foundation testimony, provided they are shown to a witness and moved into evidence as provided above.

26. A party will identify exhibits to be used in connection with examination of a witness by **7:30 p.m.** two nights before their intended use, and objections will be provided no later than

7:30 p.m. one night before their intended use. The parties shall then meet and confer on the objections by **10:00 p.m.** one night before their intended use. This provision does not apply to demonstratives created during testimony, or demonstratives, documents, or other materials to be used for cross-examination, none of which need to be provided to the other side in advance of their use. In addition, blow-ups or highlights of exhibits or parts of exhibits or testimony are not required to be provided to the other side in advance of their use.

27. If good faith efforts to resolve the objections fail, the party objecting to the exhibits shall bring its objections to the Court's attention in the morning prior to the witness being called to the stand according to the procedures *infra* §XVI.E. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of objection to the exhibit.

28. Statements from any responses to requests for admission or interrogatories, or from pleadings or admitted facts from dispositive briefing in this litigation may be read at trial, provided the complete question and answer are read. The parties agree pleadings and discovery responses need not be included on the exhibit list and are not evidence. The party planning to use such a document in its case-in-chief agrees to provide a copy of the document it intends to use in Court to the other side and identify the portions it intends to use by no later than **7:30 p.m.** two days before it will be used in Court. The other side will provide objections thereto by **9:00 p.m.** that same night, and the parties shall meet and confer by **10:00 p.m.** that same night to resolve such objections.

29. On or before the first day of trial, counsel will deliver to the Courtroom Deputy a completed AO Form 187 exhibit list for each party.

B. Demonstratives

30. The parties' demonstratives to be used at trial need not be included on their respective lists of trial exhibits to be filed with the Court. Nippon Shinyaku's and/or NS Pharma's demonstratives will be identified with **PDX** numbers. Sarepta and/or UWA's demonstratives will be identified with **DDX** numbers. Demonstratives will be exchanged by the parties pursuant to the schedule below.

31. The parties will exchange demonstratives and a list of exhibits that they intend to use in their opening statements by **2:00 p.m.** the day before opening statements are made. The parties will provide any objections to such demonstratives and exhibits by **5:00 pm** the night before opening statements are made. The parties shall meet and confer about any objections by no later than **7:00 p.m.** that night. The parties agree that any changes to these materials made after **2:00 p.m.** the day before opening statements are made will be non-substantive (e.g., edits to font, layout, format, or to correct typographical errors) unless made in response to and for the purpose of resolving an objection.

32. Demonstratives to be used on direct examination of a witness will be exchanged pursuant to the procedures set forth below. These provisions do not apply to demonstratives created during testimony or demonstratives to be used for cross-examination, neither of which need to be provided to the other side in advance of their use. The parties also are not required to identify demonstrative exhibits previously used with a witness during trial. In addition, blow-ups or highlights of exhibits or parts of exhibits or testimony that are not included within a demonstrative and used live during a witness's testimony, and which contain no additional markings, commentary, or alterations, are not required to be provided to the other side in advance of their use. In the event blow-ups, enlargements, highlights, or call outs of exhibits or testimony

include, are coupled with, or presented alongside any characterizations, labels, or the like, the below provisions regarding exchange apply.

33. A party will provide demonstratives to be used in connection with direct examination of a witness by **7:30 p.m.** the night before their intended use, with an agreement that any changes to the demonstratives made after such exchange will be only font/layout/format/to correct typographical errors and not edits of substance, unless made in response to and for the purpose of resolving an objection. Objections will be provided not later than **9:00 p.m.** the night before their intended use. The parties shall then meet and confer on the objections by **10:00 p.m.** If any of the demonstratives change after the deadline, the party intending to use the demonstrative will promptly notify the opposing side of the change(s).

34. If good faith efforts to resolve objections to demonstrative exhibits fail, the objecting party shall bring its objections to the Court's attention prior to the opening statements or prior to the applicable witness being called to the witness stand according to the procedures *infra* §XVI.E. Failure to comply with these procedures, absent an agreement by the parties or approval by the Court, will result in waiver of the use of a demonstrative or waiver of objection to the demonstrative. Nothing in the foregoing is a waiver of any objection to the testimony of a witness in connection with the demonstrative.

35. A party seeking to use a demonstrative will provide a color representation of the demonstrative to the other side in PDF or other electronic form labeled with the exhibit or demonstrative number. Any video demonstrative shall be exchanged in a manner sufficient to permit the opposing side to see the moving images and hear any included audio. Exchange of large boards is not required, and these demonstratives may be exchanged in 8½" x 11" format with the PDF/electronic exhibits being exchanged at that same time. In addition, blow-ups or highlights

of exhibits or parts of exhibits or testimony that are not included within a demonstrative and used live during a witness's testimony, and which contain no additional markings, commentary, or alterations, are not required to be provided to the other side in advance of their use.

36. Demonstrative exhibits need not be included in the sides' respective exhibit lists. Reasonable, non-substantive edits or corrections of typographical and similar errors to demonstrative exhibits may be made to such exhibits before use.

37. The parties need not exchange demonstratives to be used in closing arguments.

38. By **7:30 p.m.** two days before the side that is presenting their case-in-chief expects to rest, the resting side shall provide to counsel for the other party an estimate of when it expects to rest so that the sides have an opportunity to comply with the other notice provisions of this Order.

39. Three days before the first day of trial the parties shall make available for inspection any physical exhibits to be used at trial, labeled with an exhibit number, whether such physical exhibits will be admitted into evidence or used as demonstratives. For purposes of clarity, such physical exhibits do not include document trial exhibits or graphical demonstratives, which are subject to the disclosure provisions above.

VI. WITNESSES

40. Nippon Shinyaku's and NS Pharma's witnesses that may be called to testify at trial are identified in the attached **Exhibit 10**. Nippon Shinyaku and NS Pharma reserve the right to call witnesses identified by Sarepta and/or UWA or additional witnesses for impeachment or rebuttal or to authenticate documents.

41. Sarepta's and UWA's witnesses that may be called to testify at trial are identified in the attached **Exhibit 11**. Sarepta and UWA reserve the right to call witnesses identified by

Nippon Shinyaku and/or NS Pharma or additional witnesses for impeachment or rebuttal or to authenticate documents.

42. The listing of a witness on a side's witness list does not require the side to call that witness to testify and does not imply or establish that the listing side has the power to compel the live testimony of that witness or make that witness available to the opposing side. Any witness not listed will be precluded from testifying, absent good cause shown.

43. Each side may call a given fact witness only once during the jury trial, either live or by deposition. The parties recognize that certain fact witnesses may also testify during the bench trial on inequitable conduct. A party may go beyond the scope of their case-in-chief during direct examination of their fact witnesses and opposing counsel may go beyond the scope of the direct in their cross-examinations. Neither side will call a witness on the opposing side's witnesses list adversely. To the extent that a side does not call a witness that it has identified in its case in chief, the other side will have the ability to call that witness when it next has the floor and/or use the deposition testimony of that witness.

44. Nippon Shinyaku's and NS Pharma's list of deposition designations is attached as **Exhibit 12**. Also included in **Exhibit 12** are Sarepta's and UWA's objections and counter-designations to the testimony offered by Nippon Shinyaku and NS Pharma and Nippon Shinyaku's and NS Pharma's objections to Sarepta's and UWA's counter designations. The parties agreed to provide any objections to counter designations and any counter-counter designations as part of the designation exchanges described below. Nippon Shinyaku and NS Pharma reserve the right to add deposition designations for witnesses that Sarepta and UWA do not bring live.

45. Sarepta and UWA's list of deposition designations is attached as **Exhibit 13**. Also included in **Exhibit 13** are Nippon Shinyaku's and NS Pharma's objections and counter-

designations to the testimony offered by Sarepta and UWA and Sarepta's and UWA's objections to Nippon Shinyaku's and NS Pharma's counter-designations. The sides agreed to provide any objections to counter designations and any counter-counter designations as part of the designation exchanges described below. Sarepta and UWA reserve the right to add deposition designations for witnesses that Nippon Shinyaku and NS Pharma do not bring live.

46. These designations cover witnesses the parties anticipate may testify via deposition. Provision of deposition designations does not preclude the right of either party to call any listed witness live, subject to the disclosure provisions of the form of witness testimony outlined herein.

47. Any witness not listed on **Exhibits 10-13** will be precluded from testifying, absent good cause shown.

48. No party shall be required to present live testimony from any witness on its side's list of live witnesses.

49. Each party reserves the right to object to the relevance or admissibility of any evidence offered by another party at the time such evidence is offered and in view of the specific context in which such evidence is offered, only if that objection could not have been made timely as part of the Pretrial Order submissions because such context was not made available to the objecting party at the time. The parties are not required to designate deposition testimony to be used for impeachment. In the event that a party or side cannot or does not call any designated "will call" live witness to trial, the other side may identify additional designations to which the other party or side may object and offer counter designations. All objections and colloquy of counsel will be eliminated from the deposition designations when the designations are read to or viewed by the jury.

50. Each side will provide the other with an updated good-faith list of witnesses it intends to call live at the trial by one week before the first day of trial **by 7:00 p.m.**, without prejudice to the right to remove any such witness. Except as set forth herein, no fact or expert witness called by a side shall be permitted to testify in its case-in-chief, responsive, or rebuttal case at trial if not identified in this Order (including exhibits thereto), unless the Court determines that good cause exists for calling an unlisted witness. The listing of a witness on a side's witness list or inclusion of witness's deposition testimony on a party's list of deposition designations does not require the party to call that witness to testify live or by designation, and does not imply or establish the listed party has the power to compel the live testimony of that witness or make that witness available to the opposing party.

51. Once a side has identified a witness on its final list, if the side later elects not to call that witness, it must make a good faith effort to make that witness available to be called by the other side, if the other side so chooses. The other side may also elect to designate deposition testimony from the witness.

52. Each side will provide the other side with a list, in order of presentation, of witnesses it intends to call live on direct examination **by 7:30 p.m.** the second day before those witnesses are intended to testify in Court. (For example, if a side intends to call a witness on Wednesday, that side shall disclose that witness's name to the opposing side no later than **7:30 p.m. on Monday.**) This list must also include those witnesses who are to be called by designation (whose designations will have been previously disclosed pursuant to the procedures described below), so as to disclose the order in which any witnesses called by designation shall appear. This list is the anticipated order of the presentation of witnesses, but if there will be adjustment to the order for that particular day, the other side must be timely informed. Any objections shall be

provided by **9:00 p.m.** two days before the witness is to be called. No deviations from this notice shall be permitted except by agreement of the parties or for good cause shown. The parties shall meet and confer by **10:00 p.m.** two days before the witness is to be called to resolve any disputes, and if the objections to the disputed testimony are not resolved by the parties' meet and confer, they will be presented to the Court according to the procedures *infra* §XVI.E.

53. [**Sarepta's Proposal:**² A live witness must testify in the same language in which that witness testified at deposition. A party offering a witness who will testify in a language other than English will notify the other side that an interpreter will be used no later than one week before trial. The parties will meet and confer to agree on a mutually acceptable interpreter. The interpreter agreed upon by the parties shall have no *ex parte* communications with the parties. Neither party intends to use a check interpreter.] [**NS's Proposal**³: For all of its witnesses who

² **Sarepta's Position:** Sarepta objects to NS's plan to have *ex parte* discussions with its proposed interpreter, including having the interpreter participate in its witness preparation sessions and exposing the interpreter to privileged communications with the witness before the witness takes the stand. Sarepta contends that the interpreter should be agreed between the parties and should not have *ex parte* communications with the parties prior to or during trial. Exposure to *ex parte* and/or privileged communications will—even inadvertently—bias the interpreter's choice of language in favor of NS's theories of the case. *See Advanced Tech. Incubator, Inc. v. Sharp Corp.*, 701 F. Supp. 2d 861, 862-63 (E.D. Tex. 2010) (disqualifying defendant's interpreter at trial for the appearance of impropriety arising from translating privileged conversations preparing defendant's witnesses for deposition). Unlike witnesses, interpreters are not subject to cross-examination. Further, it is prejudicial in that the interpreter will have familiarity with NS's questions and the witness's answers during direct, and will be able to translate those questions and answers more quickly than they will be able to translate Sarepta's and/or UWA's cross examination questions. Sarepta further objects to NS's witnesses testifying partially in English if they testified in Japanese at their depositions. NS chose to have its witnesses testify fully through interpreters at their depositions and none of them tried to answer questions partially in English. (There is no indication that this was the case in the *Taiho* Order that NS cites.) Allowing them to answer questions in English on direct but only Japanese during cross is unfair and prejudicial.

³ **NS's Position:** NS proposes that interpreters be treated like witnesses and unable to have *ex parte* communications once the interpreter is interpreting a witness's testimony. Given the highly

appear on the will call witness list who testified in Japanese at their depositions, NS provides notice via this Order that such witnesses who appear live at trial will use an interpreter during testimony. Although such witnesses who did not testify in English at their deposition may have some familiarity with the English language and may try to answer some questions partially in English, they will nevertheless require translation during trial between English and their native language of Japanese. NS will provide a translator to attend trial during its witnesses who will be testifying in Japanese. Sarepta and UWA shall be permitted to have a check translator in attendance. The parties agree that an interpreter shall not have *ex parte* communications with a witness once the witness is on the stand.] With the exception of expert witnesses and a corporate representative for each party, the parties agree that fact witnesses should be prevented from hearing the testimony of other witnesses pursuant to Federal Rules of Evidence 615. Fact witnesses, however, may be present for the parties' opening statements. Excluded witnesses will be prohibited from learning about, obtaining, or being provided with trial testimony of other witnesses. Counsel for the parties shall notify one another by e-mail of their corporate representative no less than two days before the first day of trial by **7:30 p.m.**

54. The parties may offer some or all the deposition testimony set forth in their side's designations, in **Exhibits 12 & 13**, during trial, so long as the witness is unavailable as that term

technical nature of testimony anticipated to be presented from witnesses whose native language is Japanese, NS believes is both practical and fair to enable the interpreter—who will be under an oath to interpret accurately—to be exposed to and aware of the technical terms and related information for a witness's testimony. This will only serve to ensure the interpretation is most accurate and avoid needless delays with interpreters needing to pose questions on meaning of technical terms, as occurred during depositions in this case. NS's proposal that witnesses be able to testify in a combination of both English and Japanese (insofar as the witness feels comfortable and is able to do so) is consistent with how this Court has handled witnesses testifying in other languages with the assistance of an interpreter in a recent trial. *See Taiho Pharma. Co. v. Eugia Pharma Specialties Ltd.*, C.A. No. 19-2309-JLH (D. Del.), Public Version of Pretrial Order (D.I. 173), ¶ 68.

is defined under the Federal Rules. If a party decides to offer less than all the designated testimony for a witness at trial, the opposing side may use such dropped testimony as counter-designations. A party's decision not to introduce some or all the testimony of a witness designated herein shall not be commented on at trial.

55. Any deposition testimony may be used at trial for the purpose of impeachment, regardless of whether a party identified that testimony on its list of deposition designations, if the testimony is otherwise appropriate for such purpose.

56. All irrelevant and redundant material, including colloquy between counsel and objections, will be eliminated when the deposition is read or viewed at trial. The manner of using counter-designations at trial shall be in the same manner (video versus read transcripts) as that used for the designation sought to be rebutted, such that all designations and counter-designations will be played or read to the jury, as the case may be, as one consecutive segment in the order the testimony appears in the transcript. If a party offers video testimony, that party shall be responsible for including video portions of counter-designated testimony that is designated as described in this section. If a party does not offer video testimony, that party need not offer video of the other side's counter-designations. The party who originally designated the testimony may elect whether it will be played or read. [NS's Proposal]⁴ Insofar as video deposition testimony from a witness who testified in a language other than English is played, the entirety of the witnesses' testimony (including the responses provided in Japanese) shall be played to the jury so that the jury can accurately judge witness credibility. Insofar as deposition testimony from such witnesses is read,

⁴NS's Position: Permitting deposition testimony to include the deponent's response provided in the deponent's native language before playing the English translated version read by a translator is consistent with how another court has handled the issue of translated deposition testimony during trial. See *Ushijima v. Samsung Elec. Co.*, 2015 WL 5173975 (W.D. Tex. Jan. 30, 2015), Joint Final Pretrial Order, ¶¶ 32-33.

no party need to read a response provided in Japanese.] [**Sarepta's Proposal**.⁵ If a translator was used in a deposition, only portions of the testimony in English (whether original or translated) may be played or read]. Regardless of whether deposition testimony is read or played by video, the time for each side's designated portions will be charged to the designating side.

57. Each side will provide the other with a list of final deposition designations (from the previously designated testimony) that it intends to introduce by **7:30 p.m.** three days before the date on which designations are intended to be used in court, and a statement of the manner in which the prior testimony should be presented (i.e. video versus read depositions). (For example, witnesses to be called by designation on Wednesday must be disclosed by **7:30 p.m.** the preceding Sunday, along with their proposed testimony.) The other side must identify any objections to the designated testimony and any counter designations no later than **7:30 p.m.** two days before the date on which the designations are intended to be used in court. The originally designating side may identify any objections or counter-counter designations by **8:30 p.m.** that day. All designations (but not counter-designations or counter-counter designations) must have been included in **Exhibits 13 and 14**, subject to the parties' reservation of rights set forth herein *supra* ¶¶ 44-45. The sides shall then meet and confer as to any objections and any disagreement regarding

⁵ **Sarepta's Position:** Deposition testimony is difficult enough for juries to watch, and may be particularly difficult here, where the parties' interpreters at the depositions often engaged in lengthy colloquies in Japanese. Former Magistrate Judge Grewal rejected the precise argument NS makes here—that the non-English testimony must be viewed to assess credibility—holding that non-English testimony “may be edited out of the transcript/video clips for hearing/viewing by the jury.” *Corning Optical Commc 'ns Wireless Ltd. v. SOLiD, Inc.*, No. 5:14cv03750-PSG, 2015 WL 5569095, at *3 (N.D. Cal. Sept. 22, 2016); see also Pretrial Conference Tr. 43-45, *Corning Optical Commc 'ns Wireless Ltd. v. SOLiD, Inc.*, D.I. 374 (N.D. Cal. Sept. 22, 2015) (Court rejecting counsel’s argument that non-English testimony must be played “to evaluate the witness’s credibility”). Sarepta further notes that the Joint Final Pretrial Order NS relies on for support is inapposite because it appears the parties agreed to that provision. Here, the parties disagree.

the manner in which testimony should be presented no later than **10:00 p.m.** that day. Any unresolved objections will be submitted to the Court in a joint submission by **8:30 a.m.** the next morning—i.e., one day before the date on which the designations are intended to be used in court. The joint submission shall include (i) a copy of the entire proposed testimony of the witness at issue, clearly highlighting the designations; and (ii) a cover letter identifying the pending objections, as well as a brief indication (no more than one sentence per objection) of the basis for objection and the offering side's response to the objection.

58. Either side may withdraw a designation at any time, particularly as the Court may resolve disputes about designated testimony on the day on which it is to be read or played. The sides will work together in good faith to ensure that both sides can adjust designations or counter-designations accordingly.

59. Failure to comply with these procedures, absent an agreement by the parties and approval of the Court, will result in waiver of the use of the testimony or waiver of objection to the use of the testimony.

60. When deposition designations are read or played at trial, each side will be charged for the time taken to read or play its designations, as measured by the proportion of lines of testimony for its designations to the total number of lines of testimony read, or by the actual time for video testimony if played.

61. For those witnesses whose prior deposition or trial testimony will be read or played to the jury, the parties shall be permitted to make brief transition statements to introduce the witnesses and their role in the litigation. However, counsel shall not be permitted to argue or comment on the evidence during transition statements.

VII. NS'S STATEMENT OF INTENDED PROOFS

62. Nippon Shinyaku's and NS Pharma's statement of intended proof at trial is limited to the issues for which Nippon Shinyaku and/or NS Pharma bears the burden of proof at trial and does not address the proof that Nippon Shinyaku and/or NS Pharma may choose to present in rebuttal to the defenses and counterclaims that Sarepta and UWA may present in their case-in-chief or in Nippon Shinyaku's and NS Pharma's rebuttal case.

63. Nippon Shinyaku's and NS Pharma's statement is based upon the current status of the case and the Court's current rulings. Nippon Shinyaku and NS Pharma reserves the right to revise this statement based on Sarepta's and UWA's statement of intended proof or any further decisions or orders of the Court. Nippon Shinyaku and NS Pharma incorporates by reference their statements of contested facts and issues of law in **Exhibits 3 and 5**, respectively. The following statements are not exhaustive, and Nippon Shinyaku and NS Pharma reserve the right to prove any matters identified in their pleadings, infringement contentions, non-infringement contentions, validity contentions, invalidity contentions, interrogatory responses, and/or expert reports.

64. At trial, Nippon Shinyaku and/or NS Pharma intends to establish, through its presentation of evidence, that:

- a. Sarepta directly and literally infringes the Asserted Claims of the NS Patents.⁶
- b. Sarepta induces and contributes to infringement of the Asserted Claims of the NS Patents.

⁶ Because NS has advised Sarepta what specific claims of the NS Patents it is asserting infringement of for trial, via this Order, Sarepta hereby stipulates, under the Court's claim construction, to infringement of the identified claims from the NS Patents if the claims are finally adjudicated to be not invalid and not unenforceable. Sarepta reserves all appellate rights, including any finding of infringement based on the Court's claim construction or any adverse finding as to invalidity or unenforceability.

- c. Sarepta's infringement of the NS Patents was willful.
- d. The Wilton Patents are invalid as further explained in Nippon Shinyaku's and NS Pharma's statements of contested facts and law.
- e. The Wilton Patents are unenforceable due to inequitable conduct.
- f. Sarepta breached the MCA.⁷
- g. Nippon Shinyaku is entitled to damages in an amount adequate to compensate it for Sarepta's infringement, including without limitation no less than a reasonable royalty and/or lost profits.
- h. Nippon Shinyaku is entitled to an accounting for acts of infringement prior to the date judgment is entered, to the extent such damages for such infringement are not reflected in the verdict.
- i. Nippon Shinyaku is entitled to damages in an amount adequate to compensate it for Sarepta's breach of contract.
- j. Nippon Shinyaku is entitled to enhanced damages.
- k. Nippon Shinyaku is entitled to pre- and post-judgment interest of any damages award.
- l. Nippon Shinyaku is entitled to an award of attorneys' fees incurred in this litigation.
- m. Nippon Shinyaku is entitled to an award of costs and other such relief in law or equity as the Court deems just and proper.
- n. Sarepta and UWA are not entitled to any relief on their counterclaims.

⁷ Evidence regarding NS's breach of contract claim will be presented to the Court as part of a bench trial.

VIII. SAREPTA AND UWA'S STATEMENT OF INTENDED PROOFS

65. Sarepta's and UWA's statement of intended proof at trial is limited to the issues for which Sarepta and UWA bear the burden of proof at trial and does not address the proof that Sarepta and UWA may choose to present in rebuttal to the defenses and counterclaims that Nippon Shinyaku and NS Pharma may present in its case-in-chief or in Sarepta's and UWA's rebuttal case.

66. Sarepta's and UWA's statement is based upon the current status of the case and the Court's current rulings. Sarepta and UWA reserve the right to revise this statement based on Nippon Shinyaku's and/or NS Pharma's statement of intended proof or any further decisions or orders of the Court. Sarepta and UWA incorporate by reference their statements of contested facts and issues of law in **Exhibits 4 and 6**, respectively. The following statements are not exhaustive, and Sarepta and UWA reserve the right to prove any matters identified in their pleadings, infringement contentions, non-infringement contentions, validity contentions, invalidity contentions, interrogatory responses, and/or expert reports.

67. At trial, Sarepta⁸ and/or UWA intend to establish, through their presentation of evidence, that:

- a. Nippon Shinyaku and NS Pharma directly and literally infringe the Asserted Claims of the Wilton Patents.
- b. Nippon Shinyaku and NS Pharma induce and contribute to infringement of the Asserted Claims of the Wilton Patents.
- c. Nippon Shinyaku's and NS Pharma's infringement of the Wilton Patents was and is willful.

⁸ Sarepta stipulates and agrees that Counterclaim V for Nippon Shinyaku's breach of the MCA (*see D.I. 328*) shall be dismissed with prejudice.

- d. The NS Patents are invalid as further explained in Sarepta's and UWA's statements of contested facts and law.
- e. The NS Patents are unenforceable due to inequitable conduct.
- f. Sarepta and UWA are entitled to damages in an amount adequate to compensate it for Nippon Shinyaku's and NS Pharma's infringement, including without limitation no less than a reasonable royalty and/or lost profits.
- g. Sarepta and UWA are entitled to an accounting for acts of infringement prior to the date judgment is entered, to the extent such damages for such infringement are not reflected in the verdict.
- h. Sarepta and UWA are entitled to enhanced damages.
- i. Sarepta and UWA are entitled to pre- and post-judgment interest of any damages award.
- j. Sarepta and UWA are entitled to an award of attorneys' fees incurred in this litigation.
- k. Sarepta and UWA are entitled to an award of costs and other such relief in law or equity as the Court deems just and proper.
- l. Nippon Shinyaku and NS Pharma are not entitled to any relief on their counterclaims.

IX. DAMAGES

68. **Nippon Shinyaku's and NS Pharma's Position:** At trial, Nippon Shinyaku will seek damages in the form of a reasonable royalty pursuant to 35 U.S.C. § 284 and also lost profits, as set forth in its expert reports, as compensation for Sarepta's past infringement, including induced and contributory infringement, and any continuing and future infringement of the NS Patents up until the date judgment is entered. Nippon Shinyaku will also seek an accounting for

any infringement prior to the date judgment is entered, to the extent damages for such infringement are not reflected in the verdict. Nippon Shinyaku will also seek an ongoing royalty for any future infringement after the date judgment is entered. Nippon Shinyaku will further seek enhanced damages under 35 U.S.C. § 284 for Defendant's willful infringement, a post-trial accounting of damages, an award of prejudgment and post-judgment interest, an award of attorneys' fees pursuant to 35 U.S.C. § 285, and interests, costs, and disbursements as justified under 35 U.S.C. § 284 and/or Federal Rule of Civil Procedure 54. Nippon Shinyaku further seeks damages (to be proven during the bench trial portion) in the form of its attorneys' fees and costs incurred due to Sarepta's violation of the MCA, as set forth in its expert report, for Sarepta's breach of the MCA.

69. **Sarepta and UWA's Position:** At trial, Sarepta and UWA will seek damages in the form of a reasonable royalty pursuant to 35 U.S.C. § 284 and also lost profits, as set forth in its expert reports, as compensation for Nippon Shinyaku's and NS Pharma's past infringement, including induced and contributory infringement, and any continuing and future infringement of the Wilton Patents up until the date judgment is entered. Sarepta and UWA will also seek an accounting for any infringement prior to the date judgment is entered, to the extent damages for such infringement are not reflected in the verdict. Sarepta and UWA will also seek an ongoing royalty for any future infringement after the date judgment is entered, subject to further proceedings following the trial. Sarepta and UWA will further seek enhanced damages under 35 U.S.C. § 284 for Nippon Shinyaku's and NS Pharma's willful infringement, a post-trial accounting of damages, an award of prejudgment and post-judgment interest, an award of attorneys' fees pursuant to 35 U.S.C. § 285, and interests, costs, and disbursements as justified under 35 U.S.C. § 284 and/or Federal Rule of Civil Procedure 54.

X. MOTIONS IN LIMINE

70. Nippon Shinyaku's and NS Pharma's motion *in limine* No. 1, and Sarepta's and UWA's opposition thereto and NS's reply, are attached as **Exhibit 14A**. Nippon Shinyaku's and NS Pharma's motion *in limine* No. 2, and Sarepta's and UWA's opposition thereto and Nippon Shinyaku's and NS Pharma's reply, are attached as **Exhibit 14B**. Nippon Shinyaku's and NS Pharma's motion *in limine* No. 3, and Sarepta's and UWA's opposition thereto and Nippon Shinyaku's and NS Pharma's reply, are attached as **Exhibit 14C**.

71. Sarepta's and UWA's motion *in limine* No. 1, and Nippon Shinyaku's and NS Pharma's opposition thereto and Sarepta's and UWA's reply, are attached as **Exhibit 15A**. Sarepta and UWA's motion *in limine* No. 2, and Nippon Shinyaku's and NS Pharma's opposition thereto and Sarepta's and UWA's reply, are attached as **Exhibit 15B**. Sarepta's and UWA's motion *in limine* No. 3, and Nippon Shinyaku's and NS Pharma's opposition thereto and Sarepta's and UWA's reply, are attached as **Exhibit 15C**.

XI. NUMBER OF JURORS

72. There shall be eight jurors. The Court will conduct jury selection through the "struck juror" method, beginning with the Court reading voir dire to the jury panel in the courtroom, continuing by meeting with jurors individually and addressing any challenges for cause, and concluding with peremptory strikes.

XII. NON-JURY TRIAL

73. The parties agree that certain issues in this case are issues for the Court to determine, specifically: (1) whether this case is an exceptional case, and if so, whether enhanced damages, attorneys' fees, and/or costs are warranted; (2) whether the Wilton Patents are unenforceable for inequitable conduct; (3) whether the NS Patents are unenforceable for inequitable conduct; and (4) NS's breach of contract claim.

XIII. LENGTH OF TRIAL

74. This matter is scheduled for a **5-day jury trial** beginning at **9:30 a.m.** on **May 13, 2024**, with the subsequent trial days beginning at **9:00 a.m.** Until the case is submitted to the jury for deliberations, the jury will be excused each day at **5:00 p.m.**

75. The trial will be timed. The Court has determined that each party will have 11 hours allocated to their case presentation, including opening statements and closing arguments. Apr. 18, 2024 Teleconference Tr. at 19:4-9. Unless otherwise ordered, time will be charged to a side for its opening statement, direct and redirect examinations of witnesses it calls, cross-examination of witnesses called by any other party, and closing arguments. The Courtroom Deputy will keep a running total of trial time used by counsel. If any side uses all of its allotted trial time, the Court will terminate that side's trial presentation.

76. The parties agree that the presentation of evidence will proceed as follows:

- a. Opening Statements (Nippon Shinyaku and NS Pharma first, followed by Sarepta and UWA);
- b. NS's presentation of its case in chief on its asserted claims and counterclaims that are to be tried to the jury—namely, patent damages, and invalidity of the Wilton Patents.
- c. Sarepta's presentation of its case in chief on its asserted claims and counterclaims that are to be tried to the jury—namely, Nippon Shinyaku and NS Pharma's infringement of the Wilton Patents, patent damages, and invalidity of the NS Patents. Sarepta will also present evidence rebutting Nippon Shinyaku's presentation on its affirmative claims regarding infringement and damages for the NS Patents. Sarepta and UWA will also present evidence rebutting Nippon Shinyaku and NS Pharma's presentation on invalidity of the Wilton Patents.

- d. Nippon Shinyaku's and NS Pharma's presentation of evidence to rebut Sarepta's and UWA's presentation of infringement (excluding invalidity) and damages for the Wilton Patents and invalidity with respect to the NS Patents;
- e. Closing arguments (Nippon Shinyaku and NS Pharma first, followed by Sarepta and UWA).

Consistent with the Court's order (D.I. 529), the parties will present their respective inequitable conduct and unenforceability cases to the Court in a bench trial held "simultaneously with the jury trial on the patent issues, with evidence pertaining solely to inequitable conduct being presented to the Court after the jury is released at the end of each day and/or while the jury is deliberating."

Id. The bench trial can be completed allocating [Sarepta's Proposal:⁹ 2 hours to each party's presentation] [NS Proposal:¹⁰ 4 hours to each party's presentation]. The parties shall present such evidence at the convenience of the Court. [NS's Proposal:¹¹ NS reserves the right to present testimony from its expert, Dr. Kamholz, regarding PTO procedure.] [Sarepta's Proposal:¹²

⁹ Sarepta's Position: This adds a total of four hours of testimony and should be sufficient.

¹⁰ NS's Position: Given the hotly contested factual nature of the bench trial portion of this case and the necessary witnesses to prove its case, NS believes that 4 hours per side will allow both parties to fairly present their evidence. Whether the Court allows experts regarding Patent Office procedure to testify will not materially impact the length of time needed for the bench trial portion.

¹¹ NS's Position: Testimony regarding Patent Office procedure may be helpful to the Court. See, e.g., *Shire Viropharma Inc. v. CSL Behring LLC*, 2021 WL 1227097, at *18 (D. Del. Mar. 31, 2021) (determining the testimony regarding Patent Office procedure may be helpful to the Court during inequitable conduct bench trial and collecting cases within this District admitting such testimony). NS notes that it does not intend to have its Patent Office procedure expert, Dr. Kamholz, offer testimony regarding what patent law is, recognizing that this Court is well familiar with legal issues.

¹² Sarepta's Position: "[T]he judges in th[e] District [of Delaware] have a well-established practice of excluding the testimony of legal experts, absent extraordinary circumstances." *AstraZeneca*

Neither side should be permitted to bring their experts on Patent Office procedure to testify to the Court during the bench trial portion]. The parties anticipate presenting the Court with brief opening statements during the bench trial portion of the case.

XIV. MOTIONS FOR JUDGMENT AS A MATTER OF LAW

77. The parties will make motions for judgment as a matter of law (“JMOL”) orally at a subsequent break at the close of all evidence out of the presence of the jurors. The Court can then decide, based on the motions presented orally, whether to entertain argument or further briefing. The parties also agree that any renewed JMOL motions will be addressed in connection with the schedule for post-trial briefing to be set by the Court.

XV. AMENDMENT OF THE PLEADINGS

78. The parties are not seeking any amendments to the pleadings, except as noted herein regarding:

- Nippon Shinyaku’s dismissal with prejudice of its claims of infringement of the following NS Patent claims:
 - U.S. Patent No. 10,683,322, claims 1-4, 6-9 (Second Amended Complaint, Claim IX (D.I. 86); *see also* D.I. 498 (stipulating to partial dismissal with prejudice of remaining ’322 patent claims);
 - ’092 Patent, claims 1 and 2 (partial dismissal of Second Amended Complaint, Claim IV (D.I. 86)); ’461 Patent, claim 1 (partial dismissal of Second Amended

UK Ltd. v. Watson Laby's, Inc. (NV), C.A. No. 10-915-LPS, 2012 WL 6043266, at *1 (D. Del. Nov. 14, 2012) (collecting cases). No such extraordinary circumstances exist here, and it seems unlikely that such testimony would be helpful to the Court. Sarepta further notes that it tried to reach agreement with NS for each side to withdraw its patent prosecution experts to avoid burdening the Court with having to resolve the parties’ respected *Daubert* motions on Dr. Kamholz (D.I. 391, 395, 456, 489) and Mr. Hirshfeld (D.I. 423, 424, 467, 471, 472, 494, 496, 496-1, 496-2).

Complaint, Claim V (D.I. 86)); '217 Patent, claims 1-3 (partial dismissal of Second Amended Complaint, Claim VIII (D.I. 86)), '741 Patent, claims 1-2, 4-12 (partial dismissal of Second Amended Complaint, Claim VII (D.I. 86)); '106 Patent, claim 2 (partial dismissal of Second Amended Complaint, Claim VI (D.I. 86)); '361 Patent, claims 1-7 (dismissal of Second Amended Complaint, Claim III (D.I. 86); *see also* D.I. 498 (stipulating to “dismissal with prejudice of Claim III (Infringement of the '361 Patent)”).

- Sarepta’s and UWA’s dismissal with prejudice of their claims of infringement for the following Wilton Patent claims:
 - o U.S. Patent No. 9,994,851, claim 2 (partial dismissal of Second Amended Answer, Defenses, and Counterclaims, Counterclaim I (D.I. 328));
 - o U.S. Patent No. 10,227,590, claims 1-2 (Second Amended Answer, Defenses, and Counterclaims, Counterclaim II (D.I. 328)); and
 - o U.S. Patent No. 10,266,827, claims 1-2 (Second Amended Answer, Defenses, and Counterclaims, Counterclaim III (D.I. 328)).
- Nippon Shinyaku’s partial dismissal with prejudice of its claim that the Wilton Patents are invalid under 35 U.S.C. § 103 (Second Amended Complaint, Claim II, ¶¶ 87-88 (D.I. 86)).
- Sarepta’s dismissal with prejudice of its breach of contract counterclaim (D.I. 328, Counterclaim V).

XVI. ADDITIONAL MATTERS

A. Jury Notes

79. The parties agree that the jurors be permitted to take handwritten notes during the presentations of the parties and that jurors be permitted to bring these notebooks and handwritten notes into the deliberation room. The parties further propose that the jurors be instructed not to share the notebooks with each other (though they can discuss the contents of their notes) and that the notebooks be collected and destroyed after the verdict without review. No later than **4 p.m.** on the Friday before trial commences, the parties shall submit to the Court copies of a proposed juror notebook, which shall contain a copy of all the NS Patents and Wilton Patents, a tab for the preliminary jury instructions, a section for juror notes, the Court's *Markman* order, and any other materials that the parties can jointly agree should be included.

B. Handling of Confidential Information at Trial

80. The parties anticipate that the majority of the trial will be open to the public and not sealed unless a party specifically requests that a particularly sensitive portion be sealed. The parties presently anticipate making such a request for the portions of the trial regarding patent damages. If a party makes such a request, subject to the Court's approval, and for good cause shown, the courtroom shall be cleared of those individuals not qualified under the Protective Order entered in this case, except that each party's corporate representative may remain in the courtroom throughout the entirety of trial. Where such a request is approved, the party making such a request shall be charged for the entire time necessary to rule on the request and the time it takes to clear and re-open the courtroom.

81. Insofar as the Protective Order restricts the dissemination and use of any material, such restrictions shall not apply to the introduction of evidence at trial. Insofar as the MCA between Nippon Shinyaku and Sarepta restricts the dissemination and use of any material, such

restrictions shall not apply to the introduction of evidence at trial. To the extent such documents are admitted into evidence or published to the jury at trial on monitors while the trial is open to the public, this shall not constitute a violation of the Protective Order or the MCA and such documents shall no longer be subject to any restrictions under the Protective Order.

C. Federal Judicial Center Introduction to the Patent System Video

82. The parties stipulate that the video will be played as part of the Court's preliminary jury instructions, and that the time incurred in playing the video will not be charged to the parties.

D. Set-Up of Electronic and Computer Equipment

83. The parties request that the Court grant them access to the Courtroom the business day before trial begins, to allow them to set up electronic and computer devices to be used during trial.

E. Dispute Resolution Procedures

84. If after meeting and conferring, the parties are unable to resolve their objections to demonstratives, witnesses, or other evidence, the objecting party shall provide its position(s) promptly after the conclusion of the meet and confer and in no event later than 11:00 p.m. The responding party shall provide its responsive position by 11:30 p.m. By 12:00 a.m. (midnight) Delaware counsel, on behalf of the parties, shall notify the Court by email (jlh_civil@ded.uscourts.gov) of any objections to demonstratives, witnesses, or other evidence to be presented that trial day (or, in the case of deposition designations, two days before the day of anticipated use, *see supra ¶ 52*). The parties shall attach to the email a joint pleading identifying the disputes and digital copies of all relevant demonstratives, exhibits, or other evidence with the disputed passages highlighted. The parties shall state their position on each dispute in one to two sentences. By 8:15 a.m., the parties shall provide the Court with two (2) courtesy copies of the submission. The parties shall leave the courtesy copies on the lectern in the courtroom.

XVII. SETTLEMENT

85. The parties have engaged in a good faith effort to explore the resolution of the controversy by settlement, but have been unable to reach any agreement that would resolve this matter.

IT IS HEREBY ORDERED that this Final Pretrial Order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

DATED: _____

UNITED STATES DISTRICT JUDGE